JUN 6 2002

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Special 510(k): Modification to Boston Scientific Target's GDC™ Power Supply

a. Summary Of Safety And Effectiveness

Contact Person

Jim Leathley
Regulatory Affairs Project Manager
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA. 94538

Trade Name

Guglielmi Detachable Coil (GDC) Power Supply

Common Name

Occlusion Coil, accessory

Classification Name

Artificial Embolization Device (21 CFR Section 882.5950), accessory

Predicate Devices

Number	Description	Predicate for	Clearance Date
K991139 (Boston Scientific Target)	Guglielmi Detachable Coil (GDC) System with Version 4 Modifications	GDC Power Supply modifications that are the subject of this Special 510(k)	22 Dec. 1999
K001083 (Boston Scientific Target)	Guglielmi Detachable Coil (GDC) System with additional Version 4 Modifications	GDC Power Supply modifications that are the subject of this Special 510(k)	3 May 2000

Intended Use

GDC Power Supply

Boston Scientific Target's Guglielmi Detachable Coil (GDC) Power Supply is intended for use with all versions of Boston Scientific Target's Guglielmi Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

Guglielmi Detachable Coil

The Guglielmi Detachable Coil (GDC) is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:
a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

Device Description

The GDC system consists of the following items, each of which is sold separately

- GDC Power Supply
- GDC occlusion coil attached to a delivery wire
- set of GDC connecting cables
- patient return electrode
- two 9-volt batteries

The GDC is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy.

GDC coils are manufactured from a platinum / tungsten alloy wire which is wound into a primary or main coil. Depending upon the desired final configuration, the coil is either formed into a secondary helical shape (standard and Stretch Resistant GDC), vortex shape (GDC-18 Fibered VortX) or tertiary shape (3D GDC).

GDC coils are attached to a delivery wire, which consists of a ground stainless-steel core wire with a stainless-steel coil welded at the distal end and a Teflon® outer jacket. The delivery wire is similar to that employed for the predicate GDC cleared under K991139.

GDC coils are available in a range of sizes for use with either Boston Scientific Target's -10 or -18 Infusion Catheters with two tip markers.

The GDC Power Supply is a battery-operated, self-contained unit designed to initiate and control the electrolytic detachment of a GDC coil inside an aneurysm.

Each time the GDC Power Supply is turned on, the unit defaults to the 1.0 mA current setting. Pressing the "Current" switch one time changes the setting to the 0.5 mA current setting; pressing a second time changes the setting to 0.75 mA; pressing a third time returns the unit to the default 1.0 mA setting. Each time the switch is pressed, the current display flashes the new current setting.

The GDC Power Supply is designed to apply a constant current through the GDC System and to detect when coil detachment has occurred. It maintains a constant current by:

1) sensing the amount of resistance to current flow through the GDC System, and
2) adjusting the voltage needed to maintain the desired current setting. It is also designed to identify subtle changes in the way current is flowing through the GDC System and to recognize those changes which indicate detachment.

Once those patterns are identified, the GDC Power Supply signals detachment and stops the flow of current through the GDC System.

Accessories Description

Accessories consist of the following:
- Two connecting cables, one black (274 cm long), the other red (152 cm long)
- Two standard 9 volt alkaline batteries

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Technological Characteristics Comparison

GDC Power Supply

Component/Parameter	Affect on GDC Power Supply
Power	No change made which affects this attribute; same as the predicate device.
Batteries	No change made which affects this attribute; same as the predicate device.
Expected Battery Life	No change made which affects this attribute; same as the predicate device.
Red Cable	No change made which affects this attribute; same as the predicate device.
Black Cable	No change made which affects this attribute; same as the predicate device.
Current Settings	**From current settings of: 1 mA (default), 2 mA, 0.5 mA** **To current settings of: 1 mA (default), 0.5 mA, 0.75 mA**
Current	No change made which affects this attribute; same as the predicate device.
Voltage	No change made which affects this attribute; same as the predicate device.
Operating Temperature	No change made which affects this attribute; same as the predicate device.
Storage Temperature	No change made which affects this attribute; same as the predicate device.

Technological Characteristics Comparison (cont.)

GDC Power Supply

Component/Parameter	Affect on GDC Power Supply
Relative Humidity	No change made which affects this attribute; same as the predicate device.
Unit Size	No change made which affects this attribute; same as the predicate device.
Unit Weight	No change made which affects this attribute; same as the predicate device.

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Verification Test Summary Table:
Predicate GDC Device vs Modified GDC

Test or Point of Comparison	GDC with modifications described in this submission
Electromagnetic Compatibility-Radiated Susceptibility	No change made which affects this attribute; same as the predicate device.
Electromagnetic Compatibility-Radiated Emissions Class B	No change made which affects this attribute; same as the predicate device.
Electromagnetic Compatibility-Magnetic Immunity	No change made which affects this attribute; same as the predicate device.
Operating System Test (Assembly Source Code)	No change made which affects this attribute; same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Mr. James Leathley
Regulatory Affairs Project Management
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

Re: K021494
Trade/Device Name: Guglielmi Detachable Coil (GDC) Power Supply
Regulation Number: 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: May 8, 2002
Received: May 9, 2002

Dear Mr. Leathley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021494

Boston Scientific TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Guglielmi Detachable Coil (GDC) Power Supply:
1 mA, 0.5 mA and 0.75 mA current settings

Indications for Use:

Guglielmi Detachable Coil Power Supply

Boston Scientific Target's Guglielmi Detachable Coil (GDC) Power Supply is intended for use with all versions of Boston Scientific Target's Guglielmi Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021494